

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center - WO66-G609 Silver Spring, MD 20993-0002

April 14, 2016

Primus Gloves PVT Limited Jose Paul M Manager—QA & RA Plot No: 14-A, Cochin Special Economic Zone Kakkanad, Cochin, Kerala 682037 INDIA

Re: K143477

Trade/Device Name: Nitrile Patient Examination gloves, Powderfree, Blue Color

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I Product Code: LZA Dated: undated

Received: April 12, 2016

Dear Mr. Jose Paul M:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D. Clinical Deputy Director

Tejashri Purohit-Sheth, M.D. DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S. Director Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)	
K143477	
Device Name	
Nitrile Patient Examination gloves, Powderfree, Blue color	
Indications for Use (Describe)	
The Nitrile Patient Examination gloves, Powderfree, Blue coloris worn on the examiners' hand or finger to prevent contaminat	
Type of Use (Select one or both, as applicable)	
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (8/14)

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ATTACHMENT V

K143477

SUBN	MITTER	
1.1	Company Name	PRIMUS GLOVES PRIVATE LIMITED
1.2	Address	Plot No: 14-A, Cochin Special Economic Zone,
		Kakkanad, Cochin, Kerala, India - 682037
1.3	Telephone	+ 91 484 2413063
1.4	Fax	+91 484 2413089
1.5	Email	josegaul@grimusgloves.com
1.6	Contact Person	Mr. JOSE PAUL M
		MANAGER-QA & RA
OFFI	CIAL CORRESPONDE	NT
2.1	Company Name	PRIMUS GLOVES PRIVATE LIMITED
2.2	Address	Plot No: 14-A, Cochin Special Economic Zone,
		Kakkanad, Cochin, Kerala, India - 682037
2.3	Telephone	+ 91 484 2413063
2.4	Fax	+91 484 2413089
2.5	Email	josegaul@grimusgloves.com
2.6	Contact Person	Mr. JOSE PAUL M
		MANAGER-QA & RA
Prepa	aration date	14 th April, 2016
Name	e of the device	
		NITRILE PATIENT EXAMINATION
		GLOVES, POWDERFREE, BLUE COLOR
		·
4.2	Trade Name	PRIMUS NITRILE EXAMINATION GLOVES
4.3	Common Name	PATIENT EXAMINATION GLOVES
4.4	Classification	21 CFR 880.6250 PATIENT EXAMINATION GLOVES
4.5	Class	CLASS I
	1.1 1.2 1.3 1.4 1.5 1.6 OFFICE 2.1 2.2 2.3 2.4 2.5 2.6 Preparation 4.1 4.2 4.3 4.4	1.2 Address 1.3 Telephone 1.4 Fax 1.5 Email 1.6 Contact Person OFFICIAL CORRESPONDE 2.1 Company Name 2.2 Address 2.3 Telephone 2.4 Fax 2.5 Email 2.6 Contact Person Preparation date Name of the device 4.1 Device Name 4.2 Trade Name 4.3 Common Name 4.4 Classification

4.6 Product code LZA

5.0 Identification of the legally marketed predicate device

5.1	Device Name	ETS Blue Powderfree Nitrile patient exam
	glove	
5.2	510(k) Number	K121947
5.3	Company	Northstar Healthcare Holdings, 70 Sir John
		Rogerson's Quay, Dublin 2, Ireland.
5.4	Device Description	Non sterile Nitrile powderfree exam gloves
5.5	Classification	PATIENT EXAMINATION GLOVES
5.6	Class	CLASS I
5.7	Product code	LZA
5.8	Classification Panel:	General Hospital

6.0 Description of the Device

The subject device is a patient examination glove made of synthetic nitrile latex compound. It is non-sterile, powderfree and is Blue in color. The device is ambidextrous and can be worn on either the left or right hand. The device meets ASTM 06319-10: Standard specification for Nitrile Examination Gloves for Medical Application.

The subject device is substantially equivalent to legally marketed Nitrile examination gloves identified as Product code LZA.

The device is for over-the counter single use.

7.0 Indications for use

The Nitrile Patient Examination gloves, Powderfree, Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.

8.0 Summary of performance data

There is no difference in technological characteristics compared to the predicate device. Gloves are made from Nitrile latex compound, Non sterile, Powderfree and Blue in color. The gloves have the same technological characteristics compared to ASTM or equivalent standards as given below,

Characteristics	Standards	Performance of Nitrile	
		patient examination	
		gloves, Powderfree, Blue	
		color	
Freedom from Holes	ASTM 06319-10 / ASTM	Meets	
	05151-06		
Dimensions	ASTM D6319-10	Meets	
Physical Properties	ASTM D6319-10 / ASTM	Meets	
	0412-06		
Powder-free residue	ASTM 06319-10	Meets	
	Primary skin irritation	Non-irritant	
Bio-compatibility	ISO 10993-10		
	Skin/Dermal Sensitization	Non-sensitizer	
	ISO 10993-10		
Expiration dating/Shelf life	ASTM D7160-05	Three years	

Performance data of gloves based on ASTM 06319-10 and FDA 1000ml water leak test

ASTM 06319-10 and FDA 1000 ml water leak test					
				Non sterile,	
		Test	Sampling	powderfree,	
Characteristics	Test	standard	plan/Inspection	Non sterile	RESULT
			level/AQL	Nitrile	
				examination	
				gloves-	
				PRIMUS	
Freedom from	FDA 1000	ASTM	ISO 2859-1 /	PASS	PASS
Pin holes	ml water	D5151-06	G11AQL 2.5		
	leak test	(reap			
		2011)			
		ASTM	ISO 2859-1 /	> 230 mm	PASS
	Length	D6319-10	S21AQL 4.0	(240-	
				400mm)	
		ASTM	ISO 2859-1 /	70±10 mm to	PASS
Dimensions		D6319-10	S21AQL 4.0	120±10 mm	
	Width			(sizes XS to	
				XL)	
		ASTM	ISO 2859-1 /	> 0.05 mm	PASS
	Thickness	D6319-10	S21AQL 4.0	(palm &	
				finger)	
				Tensile	PASS
				strength:	
Physical	Before	ASTM	ISO 2859-1 /	> 14 Mpa	
properties	aging	D6319-10	S21AQL 4.0	Ultimate	PASS
		and ASTM		Elongation:	
		D412-06		> 500%	
				Tensile	PASS

				strength:	
	After	ASTM	ISO 2859-1 /	> 14 Mpa	
	Accelerated	06319-10	S2/AQL 4.0	Ultimate	PASS
	aging	and ASTM		Elongation:	
		0412-06		> 400 %	
		ASTM			
		D6319-10			
Powder-free	Powder-free	and ASTM	N=5	Less than 2	PASS
residue	residue	06124-06		mg per glove	
	Primary skin	ISO	Under the condition	ons of the	PASS
	irritation	10993-10	study the device i	s not an	
Biocompatibility			irritant		
	Skin/Dermal	ISO	Under the conditions of the PA		PASS
	Sensitization	10993-10	0 study the device is not a		
			sensitizer		

9.0 Summary of the technological characteristics of device compared to the legally marketed predicate device

Characteristics	PREDICATE-	SUBJECT DEVICE :	Acceptance
	510(K) :	K143477	criteria/Standard
	K121947		
Manufacturer	Northstar	PRIMUS GLOVES	
	Healthcare	PRIVATE LIMITED, Plot	
	Holdings, 70 Sir	No: 14-A, CSEZ,	
	John	Kakkanad, Cochin,	
	Rogerson's	Kerala, India -682037	
	Quay, Dublin 2,		
	Ireland.		
Product Name	ETS Blue	Nitrile Patient	Patient
	Powder Free	Examination Gloves,	examination

	Nitrile Patient	Powderfree Blue color	gloves
	Exam Gloves		
Intended Use	Intended for	Intended for medical	Medical Glove
	medical purpose	purpose that is worn on	Guidance Manual
	that is worn on	the Examiners hand to	
	the Examiners	prevent contamination	
	hand to prevent	between patient and	
	contamination	examiner	
	between patient		
	and examiner		
Indication for use	The examination	The examination gloves	Medical Glove
	gloves is a	is a disposable device	Guidance Manual
	disposable	intended for medical	
	device intended	purposes that is worn on	
	for medical	the examiners hand or	
	purposes that is	finger to prevent	
	worn on the	contamination between	
	examiners hand	patient and examiner	
	or finger to		
	prevent		
	contamination		
	between patient		
	and examiner		
Description	Non sterile	Non sterile powderfree ,	Medical Glove
	powderfree ,	examination gloves	Guidance Manual
	examination	made of nitrile and	
	gloves made of	colored blue The	
	nitrile and	textured gloves are	
	colored blue The	provided in sizes Extra	
	textured gloves	Small, Small, Medium,	

sizes Extra smooth gloves are Small, Medium, Extra Medium, Large and Large. The Extra Large smooth gloves are provided in Sizes Small, Medium, Large and Large. The Smooth gloves are provided in Sizes Small, Medium, Large and Extra Large Presentation Non sterile Non sterile gloves are gloves are provided in dispenser boxes Material Nitrile synthetic latex Size of Sterillty Mon-sterile or Sterile Non Sterile Single Use Yes Yes ASTM D 6319-10 Use Yes Yes ASTM D 6319-10 Use Norsterile or Single Use Yes Yes ASTM D 6319-10 Use Norsterile or Single Use Yes Yes ASTM D 6319-10 Use Norsterile Overall length min 240 mm width varies from 70 mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS size to 120 mm for XL size, thickness in finger		are provided in	Extra Large. The	
Medium, Extra Large and Large. The smooth gloves are provided in Sizes Small, Medium, Large and Extra Large Presentation Non sterile provided in dispenser gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile Single Use ASTM 06319-10 LZA product code Sterility Sterility Disposable/Single use ASTM D 6319-0 Meets ASTM D 70 mm for XS size to -Overall length min 240 mm, width varies from 6319-10 120 mm for XL size, thickness in finger and palm has a minimum for XL size, to 120 mm for XS size to 120 mm for XL size, size, to 120 mm for XL size, to 120		sizes Extra	smooth gloves are	
Medium, Extra Large. The smooth gloves are provided in Sizes Small, Medium, Large and Extra Large Presentation Non sterile gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile Single Use Yes Yes Yes Overall length min 240 mm ,width varies from 6319-10 Dimensions Medium, Large Extra Large Non sterile gloves are provided in dispenser Suidance Manual Medical Glove Guidance Manual Cuidance Manual Suidance Manual Suidance Manual Dividance Manual Nitrile synthetic latex ASTM 06319-10 LZA product code Sterility Sterility Meets ASTM D 6319-10 Overall length min 240 mm ,width varies from 6319-10 Overall length min 240 mm or XS size to 120 mm for XL size, Size to 120 mm for XL size, Size to 120 mm for XL size,		Small, Small,	provided in Sizes Small,	
Large. The smooth gloves are provided in Sizes Small, Medium, Large and Extra Large Presentation Non sterile provided in dispenser provided in dispenser boxes Material Nitrile synthetic latex Non-sterile or sterile Single Use Ambidextrous Neets ASTM D 6319-10 Meets ASTM D 6319-10 To mm for XS size to dispenser from palm has a minimum on the for XS size to 120 mm for XL size, with the control of the c			•	
smooth gloves are provided in Sizes Small, Medium, Large and Extra Large Presentation Non sterile gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile Single Use Yes Yes Overall length min 240 mm ,width varies from 6319-10 Meets ASTM D 6319-10 Meets ASTM D 6319-10 120 mm for XS size to Overall length min 240 mm, width varies from palm has a minimum 0.05 mm for XL size, Size to 120 mm for XL size,			_	
are provided in Sizes Small, Medium, Large and Extra Large Presentation Non sterile gloves are gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile Single Use Yes Yes Yes Overall length min 240 mm, width varies from 6319-10 For a min 240 mm, width varies from palm has a minimum for XL size, to 120 mm for XL size, to 120 mm for XL size, and to 120 mm for XL size, to 120			Ü	
Sizes Small, Medium, Large and Extra Large Presentation Non sterile gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile Single Use Yes Yes Yes Disposable/Single use ASTM D 6319-0 Meets ASTM D 6319-10 To mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS size to 120 mm for XL size, Wedical Glove Guidance Manual Medical Glove Guidance Manual Sterille Sterilley ASTM 06319-10 Medical Glove Guidance Manual Sterille Sterillity ASTM 06319-10 Disposable/Single use ASTM D 6319-0 Meets ASTM D 6319-10 -Overall length min 240 mm, width varies from 70 mm for XS size to 120 mm for XL size,				
Presentation Non sterile				
Astra Large Presentation Non sterile gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile synthetic latex Non Sterile Non Sterile Non Sterile Single Use Yes Yes Pres Pres Non Sterile Non Sterile Sterility Sterility Disposable/Single use ASTM D 6319-0 Meets ASTM D mm ,width varies from 6319-10 Overall length min 240 mm ,width varies from 6319-10 Overall length min 240 mm, width varies from palm has a minimum palm has a minimum non mor XS size to non min 240 mm, width varies from non 240 mm, width varies				
Presentation Non sterile gloves are provided in dispenser boxes Material Nitrile synthetic latex Non Sterile Non Ster				
gloves are provided in dispenser boxes Material Nitrile synthetic latex Non-sterile or sterile Single Use Yes Yes Disposable/Single use Ambidextrous Yes Yes ASTM D 6319-10 Dimensions Meets ASTM D 6319-10 Meets ASTM D 6319-10 To mm for XS size to for XL size, thickness in finger and palm has a minimum for XL size, on the size of the solution o	Presentation		Non sterile gloves are	Medical Glove
material Nitrile synthetic latex Nitrile synthetic latex LZA product code Non-sterile or sterile Single Use Yes Yes Disposable/Single use Ambidextrous Yes Yes ASTM D 6319-0 Dimensions Meets ASTM D 6319-10 Meets ASTM D 6319-10 To mm for XS size to 120 mm, width varies from palm has a minimum 70 mm for XS size to 120 mm for XL size,			· ·	
Material Nitrile synthetic latex Nitrile synthetic latex LZA product code Non-sterile or sterile Single Use Yes Yes Disposable/Single use Ambidextrous Yes Yes ASTM D 6319-0 Dimensions Meets ASTM D 6319-10 Dimensions Meets ASTM D 6319-10 Dimensions Meets ASTM D 6319-10 To mm for XS size to open min 240 mm, width varies from for XL size, thickness in finger and palm has a minimum for XL size, one of XL size, one of XL size, size to 120 mm for XL size, one of XL size, the control of XL size, one of XL size, one of XL size, the control of XL size, one of XL size, o			•	
Material Nitrile synthetic latex Non-sterile or sterile Non Sterile Non Sterile Non Sterile Non Sterile Non Sterile Non Sterile Single Use Yes Yes Yes Disposable/Single use ASTM D 6319-0 Overall length min 240 mm ,width varies from 6319-10 Dimensions Meets ASTM D 6319-10 To mm for XS size to -Overall length min 240 mm, width varies from 6319-10 120 mm for XL size, min 240 mm, width varies from palm has a minimum 70 mm for XS size to 120 mm for XL size, size to 120 mm for XL size,		1		
Non-sterile or sterile Non Sterile Non Sterile Non Sterile Non Sterile Single Use Yes Yes Disposable/Single use Ambidextrous Yes Yes Overall length min 240 mm ,width varies from 6319-10 Dimensions Meets ASTM D 6319-10 120 mm for XS size to 120 mm for XS thickness in finger and palm has a minimum 70 mm for XS size to 120 mm for XL size, 0.05 mm LZA product code Sterility Sterility Meets ASTM D 6319-0 Meets ASTM D 6319-10 70 mm for XS size to 70 mm for XS size to 120 mm for XL size,	Material	<u> </u>	Nitrile synthetic latex	ASTM 06319-10
Single Use Yes Yes Yes Disposable/Single use Ambidextrous Yes Yes Overall length min 240 mm ,width varies from 6319-10 Dimensions Meets ASTM D 6319-10 70 mm for XS size to -Overall length 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS size to 120 mm for XL size,				LZA product code
Single Use Yes Yes Yes Disposable/Single use ASTM D 6319-0 Overall length min 240 mm ,width varies from 6319-10 Dimensions Meets ASTM D 6319-10 To mm for XS size to 120 mm for XS thickness in finger and palm has a minimum 70 mm for XS 0.05 mm Disposable/Single use Disposable/Single use Weets ASTM D 6319-0 To mm for XS size to 100 mm, width varies from width varies from palm has a minimum 70 mm for XS Size to 120 mm for XL size,	Non-sterile or	Non Sterile	Non Sterile	Sterility
Ambidextrous Yes Yes Overall length min 240 mm ,width varies from 6319-10 Dimensions Meets ASTM D 6319-10 70 mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS 0.05 mm size to 120 mm for XL size,	sterile			
Ambidextrous Yes Yes Overall length min 240 mm ,width varies from 6319-10 Dimensions Meets ASTM D 70 mm for XS size to 6319-10 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS size to 120 mm for XL size,	Single Use	Yes	Yes	Disposable/Single
Overall length min 240 Meets ASTM D mm ,width varies from 6319-10 70 mm for XS size to -Overall length 6319-10 120 mm for XL size, min 240 mm, thickness in finger and palm has a minimum 70 mm for XS 0.05 mm size to 120 mm for XL size,				use
Dimensions Meets ASTM D 6319-10 Meets ASTM D 70 mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS 0.05 mm 6319-10 -Overall length min 240 mm, width varies from 70 mm for XS size to 120 mm for XL size,	Ambidextrous	Yes	Yes	ASTM D 6319-0
Dimensions Meets ASTM D 6319-10 To mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 70 mm for XS vidth varies from 70 mm for XS size to 120 mm for XL size,			Overall length min 240	Meets ASTM D
6319-10 120 mm for XL size, min 240 mm, thickness in finger and width varies from palm has a minimum 70 mm for XS 0.05 mm size to 120 mm for XL size,			mm ,width varies from	6319-10
thickness in finger and width varies from palm has a minimum 70 mm for XS 0.05 mm size to 120 mm for XL size,	Dimensions	Meets ASTM D	70 mm for XS size to	-Overall length
palm has a minimum 70 mm for XS 0.05 mm size to 120 mm for XL size,		6319-10	120 mm for XL size,	min 240 mm,
0.05 mm size to 120 mm for XL size,			thickness in finger and	width varies from
for XL size,			palm has a minimum	70 mm for XS
			0.05 mm	size to 120 mm
thickness in finger				for XL size,
				thickness in finger

		Tensile strength 14 Mpa min for before aging and 14 Mpa min for after aging Aging done at 70 ±2 deg	and palm has a minimum 0.05 mm Meets ASTM D 6319-10- Tensile strength 14 Mpa min for before aging and 14 Mpa
Tensile Strength	Meets ASTM D	C for 166±2 hrs or 100±2deg C for 22±0.3	min for after aging
. onone onongin	6319-10	hrs	Ultimate
			elongation 500 %
			min for before
			aging and 400 %
			min for after
			aging. Aging
			done at 70 ±2
			deg C for 166±2
			hrs or 100±2deg
			C for 22±0.3 hrs
		Ultimate elongation 500	Meets ASTM D
		% min for before aging	6319-10-
Ultimate	Meets ASTM D	and 400 % min for after	Ultimate
Elongation	6319-10	aging. Aging done at 70	elongation 500 %
		±2 deg C for 166±2 hrs	min for before
		or 100±2deg C for	aging and 400%
		22±0.3 hrs	min for after
			aging. Aging
			done at 70 ±2

			deg C for 166±2
			hrs or 100±2deg
			C for 22±0.3 hrs
	Meets ASTM D	Meets ASTM D 5151 -	ASTM D 5151 -06
Freedom from	5151 -06 and	06 (2011) and ASTM	(2011) and ASTM
pinholes	ASTM 06319-10	06319-10	06319-10
		Less than 2 mg per	ASTM 0 6124-
Residual Powder	Meets ASTM D	glove	06(2011) : Less
	6124-06		than 2 mg per
			glove
	Non-irritant -	Under the conditions of	Under the
	Primary Skin	the study the device is	conditions of the
Biocompatibility	Irritation In	not an irritant	study the device
Tests	Rabbits		is not an irritant
	Non-sensitizer -	Under the conditions of	Under the
ISO 10993-10	skin Sensitization	the study the device is	conditions of the
	in Guinea pigs	not a sensitizer	study the device
			is not a sensitizer
	Powderfree,	*Powderfree,	Chapter 4-
	Nitrile patient	*Nitrile Patient exam	Labeling-
	exam glove	glove	Medical Glove
	Non sterile	*Non sterile	Guidance Manual
Labeling	Single use only	*Single use only	
	Ambidextrous	*Blue color	
	Blue color	*Ambidextrous	
	Manufactured for	*Manufactured for	
	Lot No	*Lot No	
	Intended use	*Intended use	
	Quantity	*Quantity	
	Country of origin	*Country of origin	

10.0 CONCLUSION

The physical performance of the subject device is substantially equivalent to predicate K121947 and will perform according to the glove performance and biocompatibility standards referenced. Based on the intended use, physical properties and technological characteristics, the subject device is as safe, effective and performs as well as the legally marketed predicate device.